

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111
Serial Number: 10717,978
Filing Date: November 20, 2003
Title: LEAD HAVING COMPOSITE TUBING

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REMARKS

This responds to the Office Action dated September 22, 2005, and the references cited therewith.

Claims 38, 39 and 52 are amended, no claims are canceled, and claims 54-66 are added; as a result, claims 34-39 and 47-66 are now pending in this application.

Applicant respectfully submits added claims 54-66 include no new matter.

Affirmation of Election

As provisionally elected by Applicant's representative, Tom Obermark, on September 5, 2005, Applicant elects to prosecute the invention of Group 1, claims 34-39 and 47-53.

Interview Summary

Applicant thanks Examiner Mark Bockelman for the courtesy of a telephone interview on December 21, 2005 with Applicant's representative Tom Obermark. Claims 34, 38, 39, 47 and the Office Action dated September 22, 2005 were discussed. In this phone call, the Examiner clarified the 112 rejection and further explained the 102 rejections.

§112 Rejection of the Claims

Claim 39 was rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicant has amended claim 39 to more clearly recite the subject matter. No new matter is added. Reconsideration and allowance of claim 39 are respectfully requested.

§102 Rejection of the Claims

Claims 34-37 were rejected under 35 U.S.C. § 102(b) as being anticipated by Scott (U.S. Patent No. 5,005,587).

Applicant respectfully traverses the rejections of claims 34-37, for at least the following reasons. Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon* 919 F.2d 688 (Fed. Cir. 1990) (en banc), cert. denied,

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500 U.S. 904 (1991). Moreover, "For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be *identically* shown in a single reference." (Emphasis Added). *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990). Applicant respectfully submits the rejections of claims 34-37 fail because all of the elements are not identically shown in the cited reference. Applicant cannot find, for example, an outer coating of composite insulative material coated directly on at least one conductor, as recited in claim 34. Claims 35-37 depend from claim 34 and thereby include all of its limitations.

Further, pursuant to M.P.E.P. § 2131, Applicant respectfully submits that Scott fails to identically show in as complete detail, for example, an outer coating of composite insulative material coated directly on at least one conductor, as recited in claim 34, and incorporated in claims 35-37. According to M.P.E.P. § 2131, "the *identical invention* must be shown in the cited reference in as *complete detail as is contained in the claim*." (Emphasis added). *See also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1988). The Office Action states at page 4, first paragraph, "Scott teaches a braid conductor (figure 2) 43 that has a composite coating." Applicant respectfully traverses this statement in so far as it fails to properly characterize the teaching of Scott. In contrast, Scott states at column 5, lines 19-32, for example, "A polyurethane outer tube 54 is placed over braid 42 and positioned so that its distal end is adjacent to the proximal end of the Silastic® tube 38, with braid 42 passing between the adjacent ends of outer tube 54 and tube 38. A molded sleeve 56 formed of polyurethane is placed over the transition region . . . Sleeve 56 is secured with Dow Corning medical adhesive which is applied to its inner surface prior to placement on catheter 10." Applicant respectfully submits Scott does not appear to teach the *identical invention in as complete detail as is contained in claim 34*, and required by M.P.E.P. § 2131. Pursuant to M.P.E.P. § 2131, Applicant respectfully requests the Examiner show in Scott where there is teaching for, an outer coating of composite insulative material coated directly on at least one conductor, as recited in claim 34, and incorporated in claims 35-37. Absent such a showing, it appears that the Office Action relies on personal knowledge in making such an assertion. Pursuant to 37 C.F.R. § 1.104(d)(2), Applicant traverses the assertion and respectfully requests the Examiner submit an affidavit providing support for the assertion with the next Office Communication or withdraw this line of argument.

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Reconsideration and allowance of claims 34-37 are respectfully requested.

§103 Rejection of the Claims

Claims 34-37 and 47-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bush et al. (U.S. Patent No. 5,674,272) in view of Scott (U.S. Patent No. 5,005,587).

I. The Office Action Fails to Show Teaching or Suggestion for Each Element of the Claims.

Applicant respectfully traverses the rejections of claims 34-37 and 47-51. Pursuant to M.P.E.P. § 2143.03, to establish a *prima facie* case of obviousness, *all* the claim limitations must be *taught or suggested by the prior art*. Applicant can not find in the cited reference teaching or suggestion of, for example, an outer coating of composite insulative material coated directly on at least one conductor, as recited in claim 34. Claims 35-37 depend from claim 34 and thereby include all of its limitations. Additionally, Applicant can not find in the cited reference teaching or suggestion of coating a first composite insulative material between at least the first conductor and the second conductor, and coating a second composite insulative material on at least an outer surface of the second conductor, as recited in claim 47. Claims 48-51 depend from claim 47 and thereby include all of its limitations.

Moreover, absent such a showing of teaching or suggestion, Applicant assumes the Examiner is taking Official Notice of the missing elements. Pursuant to M.P.E.P. § 2144.03, “If Applicant challenges a factual assertion as not properly officially noticed or not properly based upon common knowledge, the Examiner *must* support the finding with adequate evidence. The Examiner *must* provide documentary evidence in the next Office Action if the rejection is to be maintained.” (Emphasis Added). Official Notice unsupported by documentary evidence should only be taken where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. *Id.* Further, “an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support.” *In re Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001); M.P.E.P. § 2144.03. Applicant respectfully submits there appears to be no evidence in the record to support taking Official Notice of, for example, an outer coating of composite insulative material coated directly on at least one conductor, as recited in claim 34.

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Additionally, there appears to be no evidence in the record to support taking Official Notice of coating a first composite insulative material between at least the first conductor and the second conductor, and coating a second composite insulative material on at least an outer surface of the second conductor, as recited in claim 47. To the extent Official Notice has been taken, Applicant traverses and requests a reference showing the missing elements. Alternatively, Applicant submits the assertions made are unsupported by the cited references and are within the personal knowledge of the Examiner. Applicant requests an Examiner's affidavit supporting the unsupported assertions pursuant to 37 C.F.R. 1.104(d)(2) and M.P.E.P. § 2144.03.

II. The Office Action Fails to Present a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Combine Bush with Scott.

Further, the rejections of claims 34-37 and 47-51 fail because the Office Action does not identify a proper motivation to combine Bush with Scott. According to M.P.E.P. § 2143.01, the mere fact that references *can* be modified or combined does not render the resultant modification of combination obvious unless prior art also suggests (i.e. a prior art supported objective suggestion) the desirability of modification or combination. Pursuant to M.P.E.P. § 706.02(j), “[t]he initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done.” See also *In Re San Su Lee*, 277 F.3d 1338 (CAFC 2002). Furthermore, according to M.P.E.P. § 2144, “the rationale to modify or combine the prior art . . . may be expressly or impliedly contained in the prior art or it may be *reasoned* from knowledge generally available to one of ordinary skill in the art, established scientific principles or legal precedent.” (Emphasis Added). The Office Action states at page 4, second paragraph, “Using a braid conductor for that of a coil would have been an obvious choice to those of ordinary skill in the art with Scott showing such a construction.” However, no objective support is provided for such a conclusion. Moreover, neither Bush or Scott appear to remedy the deficiency of objective support. In light of the lack of objective support, Applicant respectfully submits these statements are conclusory and do not appear to be reasoned as required by M.P.E.P. § 2144.

Applicant respectfully submits that the evidence of record does not appear to identify an objective source for the motivation to combine Bush with Scott in the manner proposed. The Office Action does not state how Bush would be in need of, for example, a plurality of

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conductors disposed within the lead body, wherein at least one of the plurality of conductors includes a braided conductor and at least one of the plurality of conductors includes a coiled conductor, as recited in claim 34 and incorporated in claims 35-37. Additionally, the Office Action does not state how Bush would be in need of providing a plurality of conductors including at least a first conductor and a second conductor, wherein at least one of the plurality of conductors includes a braided conductor and at least one of the plurality of conductors includes a coiled conductor, as recited in claim 47 and incorporated in claims 48-51. Applicant can not find any objective suggestion in Bush to employ such steps or structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to combine Bush with Scott in the manner proposed or withdraw this line of argument.

III. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because Bush and Scott Teach Away From the Claims.

Because Bush and Scott teach away from the proposed combination the Office Action does not provide a proper motivation to combine the cited references. Pursuant to M.P.E.P. § 2141.02, “Prior art must be considered in its entirety, including disclosures that teach away from the claims.” Prior art that teaches away from the claimed combination is a factor cutting against a finding of motivation to combine or modify the prior art. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path the applicant took. *In re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994); *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (C.C.P.A. 1963). Applicant submits, Bush states at column 6, lines 50-55, “[a]n inner electrical conductor 102 is tubularly and coaxially covered with an inner layer of tubing 104 . . . An intermediate coaxially oriented tubular layer 106 of impervious insulation . . . covers inner ePTFE layer 104.” Further, Scott states at column 5, lines 19-32, for example, “A polyurethane outer tube 54 is placed over braid 42 and positioned so that its distal end is adjacent to the proximal end of the Silastic ® tube 38, with braid 42 passing between the adjacent ends of outer

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tube 54 and tube 38. A molded sleeve 56 formed of polyurethane is placed over the transition region . . . Sleeve 56 is secured with Dow Corning medical adhesive which is applied to its inner surface prior to placement on catheter 10." Further still, Scott states at column 6, lines 62-64, "An outer tube 82 of an insulating material such as Silastic ® or polyurethane covers most of the length of lead 70."

Scott teaches away from the proposed combination because Scott advises using a polyurethane tube and molded sleeve secured with medical adhesive for insulation as opposed to an outer coating of composite insulative material coated directly on at least one conductor, as recited in claim 34, and incorporated in claims 35-37. Additionally, Scott teaches away from the proposed combination because Scott advises using a polyurethane tube and molded sleeve secured with medical adhesive for insulation as opposed to coating a first composite insulative material between at least the first conductor and the second conductor, and coating a second composite insulative material on at least an outer surface of the second conductor, as recited in claim 47, and incorporated in claims 48-51. Further, Bush teaches away from the proposed combination because Bush teaches using tubing for insulation as opposed to an outer coating of composite insulative material coated directly on at least one conductor, as recited in claim 34, and incorporated in claims 35-37. Further still, Bush teaches away from the proposed combination because Bush teaches using tubing for insulation as opposed to coating a first composite insulative material between at least the first conductor and the second conductor, and coating a second composite insulative material on at least an outer surface of the second conductor, as recited in claim 47, and incorporated in claims 48-51.

Because Bush and Scott teach away from the proposed combination, Applicant can not find any objective suggestion in the cited references to employ, for example, the structure or steps described above, for claims 34 and 47. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to combine Bush with Scott in the manner proposed or withdraw this line of argument.

IV. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because the Office Action Does Not Consider the Claims as a Whole.

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Further still, the rejections of claims 34-37 and 47-51 fail because the rejections do not consider the claims as a whole. According to MPEP § 2141.02, In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences *themselves* would have been obvious, but whether the claimed invention *as a whole* would have been obvious. (Emphasis in original). *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). The Office Action at page 4, second paragraph states, "While coil members are shown in Bush, applicant claims at least one is a braid member and while Bush acknowledges that they may be of any shape he does not specify a braid. Using a braid conductor for that of a coil would have been an obvious choice to those of ordinary skill in the art with Scott showing such a construction." In contrast, claim 34 recites that the lead assembly includes, *in combination with all of the elements of claim 34*, a lead body extending from a proximal end to a distal end, the lead body including a plurality of conductors disposed therein, wherein at least one of the plurality of conductors includes a braided conductor and at least one of the plurality of conductors includes a coiled conductor. Additionally, claim 47 recites that the method includes, *in combination with all of the elements of claim 47*, providing a plurality of conductors including at least a first conductor and a second conductor, wherein at least one of the plurality of conductors includes a braided conductor and at least one of the plurality of conductors includes a coiled conductor. As described above, the Office Action fails to show teaching or suggestion for this new combination. Applicant respectfully submits the Office Action merely states the differences of the claims with respect to the prior art are obvious instead of focusing on the claims as a whole. Because the rejection focuses upon the differences of the claims and not the claims as a whole, a proper *prima facie* case of obviousness has not been established.

Further, by failing to consider the invention as a whole, the Office Action uses Applicants' disclosure as a template and performs hindsight reconstruction to selectively combine Bush with Scott in the proposed manner. According to *In re Vaeck*, the teaching or suggestion to make the claimed device must be found in the prior art, not in the Appellants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Reconsideration and allowance of claims 34-37 and 47-51 are respectfully requested.

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Allowable Subject Matter

Claims 38, 52 and 53 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant respectfully submits claim 38 is rewritten in independent form including the limitations of claim 34. Further, Applicant respectfully submits claim 52 is rewritten in independent form including the limitations of claim 47. Additionally, Applicant submits claim 53 is allowable as a dependent claim of claim 52.

Reconsideration and allowance of claims 38, 52 and 53 are respectfully requested.

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 371-2117 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

JON SCHELL

By his Representatives,

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By Thomas C. Obermark
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 22 day of December, 2005.

Paula Salton
Name

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Signature